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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,292	11/19/2001	Guo-Liang Yu	PF160D2	8411

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EXAMINER	
TUNG, JOYCE	

ART UNIT	PAPER NUMBER
1637	6

DATE MAILED: 07/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/988,292	Applicant(s) YU ET AL.	
	Examiner Joyce Tung	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/26/02* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8,11,12,14,15 and 19-161* is/are pending in the application.

4a) Of the above claim(s) *1,8,11,12,14,15,44-52,80-88 and 90-161* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-43,53-79 and 89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group III, species B, claims 19-43 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that Applicants argue that no arguments have been made explaining why it would impose an undue burden to examine Groups I-VIII together, Applicants further argue that a search of the polynucleotide claims would provide useful information for the polypeptide and methods of making and using the same and in many if not most publications where a published polynucleotide is shown, the authors also include the polypeptide and methods of making and using the same. This is not found persuasive because the inventions are separately classified as set forth in the previous office action mailed 3/36/2002. Thus, a search of one invention would not be coexamine with any other. Further, the polypeptide, antibody and polynucleotide are different molecules as indicated in the Office action mailed 3/36/2002. Therefore, they are distinct inventions. Regarding the issue of method making and using the same, as indicated in the Office action mailed 3/26/2002, if the product, for example, polynucleotide or polypeptide or antibody can be used in other material different methods, the products claims are distinct over the method of making and using.

The requirement is still deemed proper and is therefore made FINAL.

Regarding the election of species of Group III, Specie B and C, claims 19-43, 53-79 and 89 are examined together because of the argument.

2. Claims 1, 8, 11-12, 14-15, 44-52, 80-88, and 90-161 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group I-II, Group III, species A, and D-F and Group IV-VIII, there being no allowable generic or linking claim.

Information Disclosure Statement

3. The references lined through in PTO 1449 filed 11/19/2001 and 4/26/2002 were not considered because the references were not provided. Specifically, the references AE, AJ and AS are not required to be listed in PTO-1449, and the references AN, AO, AQ and AR are required to have publication date.

Claim Rejections - 35 USC § 102

4 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 89 is rejected under 35 U.S.C. 102(b) as being anticipated by Oda et al. (The J. of Biological Chemistry, 1993, Vol. 268 (8), pg. 5929-5939).

Oda et al. disclose that an antibody against RI-H were raised in rabbits (See pg. 5930, column 2, third paragraph). The amino acid sequence of RI-H comprises Seq ID NO: 16 as indicated in the search report (See pg. 5934, fig. 2 and the Attached search report). It appears

that they are the same antibody since the antibody only binds to a portion of the protein and not the entire protein. This was well known in the art at the time of the instant invention. Thus, the teachings of Oda et al. anticipate the limitations of claim 89

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 19-21, 23, 41-43, 53-57, 59 and 77-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oda et al. (The J. of Biological Chemistry, 1993, Vol. 268 (8), pg. 5929-5939).

Oda et al. disclose that lactose-binding lectin in rat intestine, designated RI-H. RI-H has domain I which is N-terminal domain and domain II which is C-terminal domain (See pg. 5929, the Abstract). The cDNA sequence of RI-H and its amino acid sequence are disclosed (See pg. 5934, fig. 2). The amino acid sequence of RI-H comprises Seq ID NO: 16 as indicated in the search report (See the Attached search report). The antibody against RI-H was raised in rabbits and a hybridoma was used to producing a monoclonal antibody to L-29 (See pg. 5930, column 2, third paragraph).

Thus, the antibody used by Oda et al. is suggested to be the same antibody as claimed in the instant invention.

One of ordinary skill in the art at the time of the instant invention would have been motivated to apply the antibody of Oda et al. to against the protein whose sequence consists of amino acid residues 1-323 of SEQ ID NO:16. because it appears that they are the same antibody since antibody only binds to a portion of the protein, not the entire protein. This was well known in the art at the time of the instant invention. Thus, it would have been prima facie obvious to obtain the isolated antibody as claimed.

8. Claims 24, 30-31, 60, 66-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oda et al. (The J. of Biological Chemistry, 1993, Vol. 268 (8), pg. 5929-5939) as applied to claims 19-21, 23, 41-43, 53-57, 59, and 77-79 above, and further in view of Imani et al. (5,766,856).

The teachings of Oda et al. are set forth in section 7 above, and Oda et al. do not disclose how to produce labeled antibody and polyclonal antibody.

Imani et al. disclose soluble and membrane associated forms of Mac-2 and diagnostic assay, such as immunoassay with labeled antibodies (See the Abstract). Imani et al. also disclose how to produce monoclonal and polyclonal antibody against Mac-2 (See column 15, lines 38-48) and the labels used to label antibody (See column 13, lines 24-60) as recite in claims 67.

One of ordinary skill in the art at the time of the instant invention would have been motivated to make the labeled antibody and polyclonal antibody against the protein which sequence consists of amino acid residue 1-323 of SEQ ID NO:16 as claimed. The motivation is that Imani et al. disclose the method to make labeled antibody, and polyclonal antibody in which the target protein can be detected. It would have prima facie obvious to make the labeled antibody and polyclonal antibody as claimed.

9. Claims 22, 25-29, 32-40, 58, 61-65, 68-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oda et al. (The J. of Biological Chemistry, 1993, Vol. 268 (8), pg. 5929-5939) as applied to claims 19-21, 23-24, 30-31, 41-43, 53-57, 59-60, 66-67 and 77-79 above, and further in view of Imani et al. (5,766,856) and Co et al. (5,714,350).

The teachings of Oda et al. are set forth in section 7 above, and the teachings of Imani et al. are set forth in section 8 above. None of the references above discloses how to produce glycosylated antibody, chimeric antibody, the antibody which is Fab fragment or single chain and antibody composition with carrier.

Co et al. disclose a method of producing mutationally-altered immunoglobulin and composition containing the immunoglobulin with carrier (See the Abstract and column 11, lines 38-59). The method involves glycosylation of the antibody. The advantage of the glycosylation increases the affinity and specificity of the binding to an antigen (See column 3, lines 1-23 and column 19, claims 1-4). Co et al. also indicate that the references disclosing producing the antibody which is Fab fragment or single chain (See column 5, lines 16-25). The method further involves using humanized antibody and chimeric antibody (See column 13, lines 43-57).

One of ordinary skill in the art at the time of the instant invention would have been motivated to apply the teachings of Co et al. to make glycosylated antibody, chimeric antibody, the antibody having Fab or single chain and the antibody composition with carrier with a reasonable expectations of success. The motivation is that Co et al. explicitly explained the advantage of glycosylating an antibody which increases the affinity and specificity of the binding to an antigen (See column 3, lines 1-23 and column 19, claims 1-4), the technic of making the chimeric antibody, the antibody having Fab or single chain and the pharmaceutical composition which is useful for parenteral administration (See column 11, lines 38-41). Thus, one of ordinary skill in the art at time of the instant invention would have made the composition containing the antibody with carrier because of the teachings discussed above. It would have been prima facie obvious to make the antibody and composition as claimed.

10. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

July 12, 2002

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
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